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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/107,979	06/30/98	GODOWSKI	P F1084R1-2

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HM12/0718

EXAMINER

LEE, L

ART UNIT	PAPER NUMBER
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1645

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DATE MAILED: 07/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/107,979

Applicant(s)

Godowaki et al

Examiner

LI Lee

Group Art Unit

1645

☒ Responsive to communication(s) filed on May 8, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 30-32 and 39-44 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☒ Claim(s) 30 and 42 is/are allowed.

☒ Claim(s) 31, 32, and 39-41, 43-44 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. Applicant's amendment filed on May 4, 2000 (Paper Number 10) has been received and entered. Claims 1-29 and 33-38 have been canceled, claims 30 and 31 have been amended, and new claims 39-44 have been added, consequently claims 30-32, 39-44 are pending in the instant application.
2. The rejection of claims 29-32 under 35 U.S.C. 112, second paragraph, as being indefinite for depending from non-elected claim 1 is withdrawn in view of Applicant's amendment.
3. The rejection of claims 29 and 31-32 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide of SEQ ID NO:4, does not reasonably provide enablement for any variant of polypeptide of SEQ ID NO:4 is withdrawn in view of Applicant's amendment.
4. The rejection of claims 29 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Wei-Hsien Ho et al (WO 96/15244, May 23, 1996) is withdrawn in view of Applicant's amendment.
5. The rejection of claims 29 and 31-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Capon et al (US 5714147, Feb 3, 1998) is withdrawn in view of Applicant's amendment.

New Grounds of Rejections Based on the Applicant's Amendment

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 31-32, 39-41, and 43-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31 recites the limitation "the immunoglobulin sequence" in claim 31. There is insufficient antecedent basis for this limitation in the claim.

Claim 41 is indefinite for reciting "ATCC deposit 209155" in the claim which is not disclosed in the specification. One ordinary skilled in the art cannot determine when the claimed metes and bounds can be met.

Claims 39-41 are indefinite as there is no defined specific polynucleotide sequence in the claims. Without reciting a specific polynucleotide sequence, one cannot isolate or make the polypeptide which is encoded by the polynucleotide from a ATCC deposit due to the unknown complete sequence of the deposit and one of ordinary skill in the art would not be reasonably be apprised of the metes and bounds of the claimed subject matter. Amendment of claims to recite the specific SEQ ID NO for the claimed nucleic acid sequence would obviate this rejection.

The claim 41 is read by Examiner as a typographic error for ATCC deposit 209297.

Claims 43-44 are indefinite for reciting "native glycosylation" in the claims. The term "native glycosylation" is not defined for the claimed polypeptide in the claim or the specification. Moreover, there is no biological function or chemical structure for the claimed native glycosylation in the claim or the specification. One ordinary skilled in the art cannot determine when the claimed metes and bounds can be met. Claim 44 is further indefinite for using the term

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“glycosylated in a pattern” which is not defined in the claim or the specification. Moreover, there is no biological function or chemical structure for the claimed glycosylated in a pattern in the claim or the specification. One ordinary skilled in the art cannot determine when the claimed metes and bounds can be met.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 39-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the NRG3 nucleic acid sequence in ATCC deposit number 209156, in ATCC deposit 209157, and in ATCC deposit 209297 (claim 41 is read by Examiner as a typographic error for ATCC deposit 209297) are required to practice the claimed invention. As such NRG3 nucleic acid sequence must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. If it not so obtainable or available, the requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of said strain.

It does not appear that the NRG3 nucleic acid sequence is both known and readily available or can be reproducibly made or isolated from nature without undue experimentation, and because claims 39-41 specifically require the NRG3 nucleic acid sequence in ATCC deposit

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number 209156, in ATCC deposit 209157, and in ATCC deposit 209297, a suitable deposit of the NRG3 nucleic acid sequence may be made to satisfy enablement for patent purposes.

Applicants' referral to the deposit of ATCC deposit numbers 209156, ATCC deposit 209157, and ATCC deposit 209297 at page 91-92 of the specification is noted but is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant deposit materials will be irrevocable and without restriction released to the public upon the issuance of a patent, would satisfy the requirement made herein. If a deposit has not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

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(e) the deposit will be replaced if it should ever become inviable.

This requirement if necessary when a deposit is made under the provisions of the Budapest Treaty as the Treaty leaves these specific matters to the discretion of each member State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

10. Claims 43-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

To claims 43-44 the specification as originally filed fails to provide written support for the polypeptide unaccompanied by native glycosylation and the polypeptide is glycosylated in a pattern other than native glycosylation. This issues is best resolved by applicant pointing to the specification by page and line number where the written description support for the now claimed radical interceptor can be found.

Conclusion

11. Claims 30 and 42 are allowable. Claims 31-32, 39-41, and 43-44 stand rejected.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee
July 17, 2000


PHUONG T. BUI
PRIMARY EXAMINER